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SMITH, CAROLYN L				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary****Application No.**

10/552,665

**Applicant(s)**

REESE ET AL.

**Examiner**

Carolyn Smith

**Art Unit**

1631

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 2,3,13,14,17,20,22,23 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-12,15,16,18,19,21,24 and 25 is/are rejected.
- 7) ☒ Claim(s) 6 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 October 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-849)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicant's election without traverse of Group I (claims 1-21 and 24-25) and species B, H, M, general medical physiological values, P, R, and S, filed 8/25/08, is acknowledged. Claims 22-23 and 26 are withdrawn from consideration as being drawn to non-elected Groups. Claims 2, 3, 13, 14, 17, 20 are withdrawn from consideration as being drawn to non-elected species. Applicant proposes that additional species would not be an undue burden for the first three specie election requirements. These statements are found unpersuasive for reasons given in the restriction, mailed 3/25/08. It is noted that the first specie election is directed to what is recited in the claims, not the specification. The requirements are still deemed proper and are therefore made FINAL.

Drawings, filed 10/11/05, are accepted by the Examiner.

Claims herein under examination are 1, 4-12, 15-16, 18-19, 21, 24, and 25.

#### ***Specification***

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, such as on page 26, line 7. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

#### ***Priority***

If applicant desires to claim the benefit of prior-filed applications (i.e. 60/461740 and 60/492707) under 35 U.S.C. 119(c), a specific reference to the prior-filed applications in

compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet.

If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was

unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

### ***Claim Objections***

Claim 6 is objected to because of the following informality:

Claim 6 recites “markers markers” in line 2 which is awkward.

Appropriate correction is required.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 4-12, 15-16, 18-19, 21, 24, and 25 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1, 4-12, 15-16, 18-19, 21, 24, and 25 are drawn to a process that includes embodiments that are entirely mental steps. The United States Court of Appeals for the Federal Circuit ruled in *In Re Stephen W. Comiskey* (84 USPQ2d 1670 (Fed. Cir. 2007)) that claimed subject matter drawn to mental steps were not eligible subject matter under 35 U.S.C. 101, and provided basis for the ruling as follows:

The Supreme Court has reviewed process patents reciting algorithms or abstract concepts in claims directed to industrial processes. In that context, the Supreme Court has held that a claim reciting an algorithm or abstract idea can state statutory subject matter only if, as employed in the process, it is embodied in, operates on, transforms, or otherwise involves another class of statutory subject matter, i.e., a machine, manufacture, or composition of matter. 35 U.S.C. §101. As the PTO notes, “[t]he Supreme Court has recognized only two instances in which such a method may qualify as a section 101 process: when the process ‘either [1] was tied to a particular apparatus or [2] operated to change materials to a ‘different state or thing.’” See PTO Supp. Br. 4 (quoting *Flook*, 437 U.S. at 588 n.9). In *Diehr*, the Supreme Court confirmed that a process claim reciting an algorithm could state statutory subject matter if it: (1) is tied to a machine or (2) creates or involves a composition of matter or manufacture.<sup>12</sup> 450 U.S. at 184. There, in the context of a process claim for curing rubber that recited an algorithm, the Court concluded that “[t]ransformation and reduction of an article ‘to a different state or thing’ is the clue to the patentability of a process claim that does not include particular machines.” *Id.* (quoting *Benson*, 409 U.S. at 70);<sup>13</sup> see also *In re Schrader*, 22 F.3d 290, 295 [30 USPQ2d 1455] (Fed. Cir. 1994) (holding when a claim does not invoke a machine, “§101 requires

some kind of transformation or reduction of subject matter”). Thus, a claim that involves both a mental process and one of the other categories of statutory subject matter (i.e., a machine, manufacture, or composition) may be patentable under §101. *See Diehr*, 450 U.S. at 184 (holding a process that involved calculations using the “Arrhenius equation” patentable because the claim “involve[d] the transformation of an article, in this case raw, uncured synthetic rubber, into a different state or thing”). For example, we have found processes involving mathematical algorithms used in computer technology patentable because they claimed practical applications and were tied to specific machines.<sup>14</sup>

<sup>12</sup> Of course, process claims not limited to claiming an abstract concept or algorithm (i.e., a mental process) may not be subject to the same requirements.

<sup>13</sup> *See also Diehr*, 450 U.S. at 184 (“Industrial processes ... are the types which have historically been eligible to receive the protection of our patent laws.” (emphasis added)); *Tilghman v. Proctor*, 102 U.S. 707, 722 (1880) (“A manufacturing process is clearly an art, within the meaning of the law.” (emphasis added)); *Cochrane v. Deener*, 94 U.S. 780, 788 (1876) (“A process is a mode of treatment of certain materials to produce a given result. It is an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing.”).

<sup>14</sup> *See AT&T*, 172 F.3d at 1355, 1358 (holding patentable “a process that uses the Boolean principle in order to determine the value of the PIC indicator” and that “require[d] the use of switches and computers”); *State Street Bank*, 149 F.3d at 1373 (“[W]e hold that the transformation of data ... by a machine through a series of mathematical calculations into a final share price, constitutes a practical application of a mathematical algorithm.” (emphases added)); *Alappat*, 33 F.3d at 1544 (“This is not a disembodied mathematical concept which may be characterized as an ‘abstract idea,’ but rather a specific machine to produce a useful, concrete, and tangible result.” (emphases added)); *Arrhythmia Research Tech., Inc. v. Corazonix Corp.*, 958 F.2d 1053, 1058-59 [22 USPQ2d 1033] (Fed. Cir. 1992) (holding patentable a method for analyzing electrocardiograph signals for the detection of a specific heart condition that used “electronic equipment programmed to perform mathematical computation”). However, mental processes—or processes of human thinking—standing alone are not patentable even if they have practical application. The Supreme Court has stated that “[p]henomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work.” *Benson*, 409 U.S. at 67 (emphasis added). In *Flook* the patentee argued that his claims did not

seek to patent an abstract idea (an algorithm) because they were limited to a practical application of that idea—updating “alarm limits” for catalytic chemical conversion of hydrocarbons. 437 U.S. at 586, 589-90. The Court rejected the notion that mere recitation of a practical application of an abstract idea makes it patentable, concluding that “[a] competent draftsman could attach some form of post-solution activity to almost any mathematical formula.” *Id.* at 590. Since all other features of the process were well-known, including “the use of computers for ‘automatic monitoring-alarming,’” the Court construed the application as “simply provid[ing] a new and presumably better method for calculating alarm limit values.” *Id.* at 594-95. The Court held the application unpatentable because “if a claim [as a whole] is directed essentially to a method of calculating, using a mathematical formula, even if the solution is for a specific purpose, the claimed method is nonstatutory.” 437 U.S. at 595 (quoting *In re Richman*, 563 F.2d 1026, 1030 [195 USPO 340] (CCPA 1977)).

Following the lead of the Supreme Court, this court and our predecessor court have refused to find processes patentable when they merely claimed a mental process standing alone and untied to another category of statutory subject matter even when a practical application was claimed. In *Schrader* we held unpatentable a “method constitut[ing] a novel way of conducting auctions” by allowing competitive bidding on a plurality of related items. 22 F.3d at 291. In doing so, we rejected the patentee’s argument that the process used a machine. Two of the alleged machines—a “display” in the front of the auction room and “a closed-circuit television system” for bidders in different cities—were not claimed by the patent, and the third—a “record” in which bids could be entered—could be “a piece of paper or a chalkboard.” *Id.* at 293-94. We therefore concluded that the patent impermissibly claimed unpatentable subject matter. Similarly, in *In re Warmerdam*, 33 F.3d 1354 [31 USPO2d 1754] (Fed. Cir. 1994), we held unpatentable a process for controlling objects so as to avoid collisions because the key steps of “locating a medial axis” and “creating a bubble hierarchy” described “nothing more than the manipulation of basic mathematical constructs, the paradigmatic ‘abstract idea.’” *Id.* at 1360. A machine was not required, *id.* at 1358, nor was there any indication that the process operated on a manufacture or composition of matter.

Decisions of our predecessor court are in accord. *In re Meyer*, 688 F.2d 789, 796 [215 USPO 193] (CCPA 1982), held that “a mental process that a neurologist should follow” was not patentable because it was “not limited to any otherwise statutory process, machine, manufacture, or composition of matter.” *Id.* at 795. Similarly, *In re Maucorps*, 609 F.2d 481 [203 USPO 812] (CCPA 1979), held that an invention “[u]ltimately ... directed toward optimizing the



organization of sales representatives in a business” was unpatentable. *Id.* at 482, 486. *See also Alappat*, 33 F.3d at 1541 (“*Maucorps* dealt with a business method for deciding how salesmen should best handle respective customers and *Meyer* involved a ‘system’ for aiding a neurologist in diagnosing patients. Clearly, neither of the alleged ‘inventions’ in those cases falls within any §101 category.”).<sup>15</sup>

<sup>15</sup> In *Musgrave*, our predecessor court concluded that the claims at issue in that case included non-mental steps and claimed patentable subject matter. 431 F.2d at 893. To the extent that language in the opinion might suggest that mental processes standing alone are patentable, the broad language in the opinion was significantly cabined by *Benson*. *See 1 Chisum on Patents* §1.03[6][c].

[ 2 ] It is thus clear that the present statute does not allow patents to be issued on particular business systems—such as a particular type of arbitration—that depend entirely on the use of mental processes. In other words, the patent statute does not allow patents on particular systems that depend for their operation on human intelligence alone, a field of endeavor that both the framers and Congress intended to be beyond the reach of patentable subject matter. Thus, it is established that the application of human intelligence to the solution of practical problems is not in and of itself patentable

To qualify as a statutory process, instant claims 1, 4-12, 15-16, 18-19, 21, 24, and 25 should positively recite the other statutory class (the thing or product) to which it is tied, for example by identifying the apparatus that accomplishes the method steps, or positively recite the subject matter that is being transformed, for example by identifying the material that is being changed to a different state or thing. Nominal data gathering or post solution activity steps in the claimed subject matter will not be considered sufficient to convert a process that otherwise recites only mental steps into statutory subject matter. Preamble limitations that require the claimed process to comprise machine implemented steps will not be considered sufficient to convert a process that otherwise recites only mental steps into statutory subject matter. The applicants are cautioned against introduction of new matter in an amendment.

Claims 1, 4-8, 24, and 25 are drawn to a process. A statutory process must include a step of a physical transformation, or produce a useful, concrete, and tangible result (*State Street Bank & Trust Co. v. Signature Financial Group Inc.* CAFC 47 USPQ2d 1596 (1998), *AT&T Corp. v. Excel Communications Inc.* (CAFC 50 USPQ2d 1447 (1999))). Instant claims 1, 4-8, 24, and 25 do not result in a physical transformation, thus the Examiner must determine if the instant claims include a useful, concrete, and tangible result.

As noted in *State Street Bank & Trust Co. v. Signature Financial Group Inc.* CAFC 47 USPQ2d 1596 (1998) below, the statutory category of the claimed subject matter is not relevant to a determination of whether the claimed subject matter produces a useful, concrete, and tangible result:

The question of whether a claim encompasses statutory subject matter should not focus on *which* of the four categories of subject matter a claim is directed to 9-- process, machine, manufacture, or composition of matter--but rather on the essential characteristics of the subject matter, in particular, its practical utility. Section 101 specifies that statutory subject matter must also satisfy the other "conditions and requirements" of Title 35, including novelty, nonobviousness, and adequacy of disclosure and notice. *See In re Warmerdam* , 33 F.3d 1354, 1359, 31 USPQ2d 1754, 1757-58 (Fed. Cir. 1994). For purpose of our analysis, as noted above, claim 1 is directed to a machine programmed with the Hub and Spoke software and admittedly produces a "useful, concrete, and tangible result." *Alappat* , 33 F.3d at 1544, 31 USPQ2d at 1557. This renders it statutory subject matter, even if the useful result is expressed in numbers, such as price, profit, percentage, cost, or loss.

In determining if the claimed subject matter produces a useful, concrete, and tangible result, the Examiner must determine each standard individually. For a claim to be "useful" the claim must produce a result that is specific and substantial. For a claim to be "concrete" the process must have a result that is reproducible. For a claim to be "tangible" the process must produce a real world result . Furthermore, the claim must be limited only to statutory embodiments.

Claims 1, 4-8, 24, and 25 do not require production of a tangible result in a form that is useful to the user of the process. The claims determine the probability of exhibiting one or more phenotypic attributes without requiring that the probability be outputted to a user in a user interpretable format. A tangible result requires that the claims must set forth a practical application to produce a real-world result. This rejection could be overcome by amendment of the claims to recite that a result of the process is outputted to a display, or to a user, or in a graphical format, or in a user readable format, or by including a result that is a physical transformation. The applicants are cautioned against introduction of new matter in an amendment.

***Claims Rejected Under 35 U.S.C. § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4-12, 15-16, 18-19, 21, 24, and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Claims 1 and 9 recite the term “zygosity” which is vague and indefinite. It is unclear how Applicants intend to define this term. It is unclear if zygosity is referring to homozygosity, heterozygosity, hemizygosity, whether twins are identical or fraternal, or various other scenarios. Claims 4-8, 10-12, 15-16, 18-19, 21, and 24-25 are also rejected due to their dependency from

claims 1 and 9.

Claim 9 (lines 5-6) recite the phrase “the characteristic” which lacks clear antecedent basis. The claim mentions genomic characteristics as well as one or more phenotypic characteristics, so it is unclear what particular characteristic is being referred to in “the characteristic”. Claims 10-12, 15-16, 18-19, and 21 are also rejected due to their dependency from claim 9.

Claims 24 and 25 recite the phrase “is used for” which is vague and indefinite. This limitation is a passive step. It is unclear what active method step is intended to be represented by this limitation.

### ***Claim Rejections – 35 USC §102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4-12, 15-16, 18-19, 21, 24, and 25 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Blumenfeld et al. (US 6,528,260 B1).

Blumenfeld et al. disclose a method for determining whether an individual has an enhanced probability of exhibiting a phenotypic attribute (col. 9, fourth paragraph; col. 67, third paragraph; col. 80, last two paragraphs; col. 84, first two paragraphs), as stated in the preamble of instant claim 1 as well as the determining step of instant claim 9. Blumenfeld et al. disclose evaluating genomic markers from a preselected set of markers (col. 10, fourth paragraph; col. 16, last paragraph to col. 17, first paragraph; col. 67, third paragraph; col. 84, second paragraph), comparing markers to a multivariate scoring matrix to obtain a matrix score that correlates patterns (col. 31, 32, and col. 83, second paragraph) as well as determining whether a marker score indicates high probability of exhibiting a phenotypic attribute (col. 84, second paragraph; col. 91, second paragraph), as stated in instant claims 1, 9. Blumenfeld et al. disclose using promoter sequences (col. 10, last paragraph; col. 31, first paragraph; col. 64, fifth paragraph), as stated in instant claims 4 and 5. Blumenfeld disclose selecting markers prioritized by degree of phenotypic significance and markers that map at least about 1000 discrete loci (col. 39, last paragraph to col. 40, first paragraph; col. 79, third paragraph; col. 89, line 47 to col. 90, first paragraph), as stated in instant claim 7. Blumenfeld et al. disclose performing analysis when some information concerning the biology of the trait is available (col. 21, second paragraph) and selecting markers from some of the Tables (i.e. 11A-B; col. 12, third paragraph; col. 17, first three paragraphs; col. 25, second paragraph) which represents scoring matrix prioritizing markers with respect to criteria of quality of supporting research, as stated in instant claim 8. Blumenfeld et al. disclose assessing individual risk (col. 9, first paragraph), screening markers with higher probabilities (col. 65, lines 53-55; col. 87, lines 60-67), identifying genotypic characteristics of an individual that correlate with phenotypic characteristics (claim 1 col. 9, first

paragraph; col. 10, fourth paragraph; col. 67, third paragraph; col. 80, last two paragraphs), displaying output to a user (col. 98, last paragraph) and accessing information on the computer (col. 97, last paragraph), as stated in instant claim 9. Blumenfeld et al. disclose genotyping individuals for a DME-related biallelic marker that is selected individually or in combination with other markers (col. 13, last paragraph), detecting an association between an allele and a phenotype (col. 14, second paragraph), reiterating experiments at least 100 times (col. 90, fourth paragraph), looking at various phenotypic trait selection criteria, such as clinical phenotype, age, family history, and severity (col. 84, second paragraph) as well as other criteria such as drug treatment responses, including drug treatments having different degrees of response or side effects (col. 84, last two paragraphs), determining probabilities of phenotypes (col. 84, second paragraph), formatting tables of information, and outputting to a user (i.e. col. 98, last paragraph; col. 103, last paragraph; Tables 10, 11A-B, 21, 22, 23), analysis regarding probability that person with a given genotype will exhibit a trait (col. 9, fourth paragraph), as stated in instant claims 9, 10, 15, 16, (and i.e. see Tables above, inherently prior to communication to individual, the identity of individual is not associated with data, as stated in instant claim 21). Blumenfeld et al. disclose studying physiological consequences at the cellular and organism level (col. 45, last paragraph to col. 46, first paragraph), various databases with information on sequence variations and how genotypes affect common diseases, drug responses, and other complex phenotypes (col. 111, first and third paragraphs), and user-specified thresholds of significance (col. 32, first paragraph) as stated in instant claims 11 and 12. Blumenfeld et al. disclose taking into account effects of subpopulations with discriminatory potential or considering close familial relationships (col. 110, second paragraph) which represents an organizational matrix that groups phenotypic

characteristics related to similar physiological systems together, as stated in instant claim 18. Blumenfeld et al. disclose assessing risk to better target therapeutic strategies defining individual drug usage based on benefit/risk prognosis as well as efficacy/tolerance prognosis (col. 9, first paragraph) and scoring the results of determination of the identity of a nucleotide at a marker with respect to the test subject's risk of contracting disease, drug response, or chances of suffering side effects (col. 41, second paragraph) which represents ranking phenotypic characteristics as a function of potential impact on the individual's lifestyle, as stated in instant claim 19. Blumenfeld et al. disclose characteristics of genomic ethnicity of an individual (col. 64, last paragraph; col. 95, fifth paragraph). Blumenfeld et al. disclose diseases including disorders of male infertility (col. 27, first paragraph) and studies among affected relatives by analysis of two individuals, including sib pair analysis (col. 80, second paragraph). Blumenfeld et al. disclose population-based association studies (col. 83, last paragraph) and inclusion criteria for selection as well as linkage studies and statistical analysis (col. 83, second to last paragraph to col. 85, last paragraph), and pharmacogenomic analysis (col. 1, second paragraph), as stated in instant claims 24 and 25.

Thus, Blumenfeld et al. anticipate the instant invention.

### ***Conclusion***

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The

faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on (571) 272-0720.

November 3, 2008

/Carolyn Smith/  
Primary Examiner  
AU 1631